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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------|----------------|----------------------|---------------------|------------------|
| 10/734,063 | 12/10/2003 | Jon Carl Marlowe | 9301-232-999 | 9078 |
| 20583 JONES DAY | 590 03/27/2009 | | EXAMINER | |
| 222 EAST 41ST ST | | | SIMS, JASON M | |
| NEW YORK, | NY 10017 | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/27/2009 | PAPER |

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JON C. MARLOWE, ELIZABETH A. WEST, HIENTHUC PHAN, and EMILY R. SCHULTZ

Appeal 2008-3527 Application 10/734,063¹ Technology Center 1600

Decided: March 27, 2009²

Before ERIC B. GRIMES, JAY P. LUCAS, and CAROLYN D. THOMAS, Administrative Patent Judges.

C. THOMAS, Administrative Patent Judge.

DECISION ON APPEAL

 $^{^{\}rm 1}$ Application filed December 10, 2003. The real party in interest is Rosetta Inpharmatics LLC.

² The two-month time period for filing an appeal or commencing a civil action, as recited in 37 CFR § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date.

I. STATEMENT OF THE CASE.

Appellants appeal under 35 U.S.C. § 134 from a final rejection of claims 14-22 mailed November 30, 2006, which are all the claims remaining in the application. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

A. INVENTION

Appellants invented a computer implemented method for generating a binding-ready biological sample and work instructions for preparing the binding-ready biological sample. (Spec., Abstract.)

B. ILLUSTRATIVE CLAIM

The appeal contains claims 14-22. Claims 1-13 and 23-25 are cancelled. Claim 14 is the only remaining independent claim. Claim 14 is illustrative:

- A computer implemented method for preparing a binding-ready biological sample for a binding assay, comprising: receiving a binding assay design for a binding assay;
- preparing an experiment design for generating a bindingready biological sample to be used in said binding assay;
- choosing a robot method for generating said bindingready biological sample;
- generating work instructions for generating said bindingready biological sample based on said experiment design and said robot method; and
- executing said work instructions on robot stations to generate the binding-ready biological sample.

C. REFERENCES

The references relied upon by the Examiner in rejecting the claims on appeal are as follows:

Bluestein US 4,780,423 Oct. 25, 1988 Lucas US 6,996,538 B2 Feb. 7, 2006

(Filed Mar. 7, 2001)

D. REJECTION

The Examiner entered the following rejection which is before us for review:

Claims 14-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bluestein in view of Lucas.

II. PROSECUTION HISTORY

Appellants appealed from the Final Rejection and filed an Appeal Brief (App. Br.) on August 7, 2007. The Examiner mailed an Examiner's Answer (Ans.) on November 30, 2007. Appellants filed a Reply Brief (Reply Br.) on January 30, 2008.

III. FINDINGS OF FACT

The following findings of fact (FF) are supported by a preponderance of the evidence.

Bluestein

- 1. Bluestein discloses providing improved solid supports for heterogeneous fluorescence immunoassays (col. 4, 1l. 5-10).
- 2. Bluestein discloses "using an IMMOPHASE radioimmunoassay kit . . . wherein the sample, a radiolabeled anti-ferritin antibody, and

an anti-ferritin antibody coupled to CPG glass through organosilane linkages are incubated together" (col. 6, ll. 36-43).

- Bluestein discloses an automated fluorescence immunoassay system using the SCREEN MACHINE system (col. 8, Il. 61-64).
- 4. In Bluestein, "Pandex's SCREEN MACHINE automatically performs particle concentration fluorescence immunoassays" (col. 9, ll. 1-3).

IV. PRINCIPLES OF LAW

Appellants have the burden on appeal to the Board to demonstrate error in the Examiner's position. *See In re Kahn*, 441 F.3d 977, 985-86 (Fed. Cir. 2006) ("On appeal to the Board, an applicant can overcome a rejection [under § 103] by showing insufficient evidence of *prima facie* obviousness or by rebutting the *prima facie* case with evidence of secondary indicia of nonobviousness.") (quoting *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998)). Therefore, we look to Appellants' Brief to show error in the proffered prima facie case. Only those arguments actually made by Appellants have been considered in this decision. Arguments which Appellants could have made but chose not to make in the Brief have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

V. ANALYSIS

Common Feature In All Claims

The only independent claim, claim 14, recites, *inter alia*, "preparing an experiment design for generating a binding-ready biological sample to be used in said binding assay."

The Obviousness Rejection

We now consider the Examiner's rejection of claims 14-22 under 35 U.S.C. § 103(a) as being obvious over the combination of Bluestein and Lucas.

The Examiner found that the second step of claim 14, noted *supra*, is taught by Bluestein in column 8, lines 10-31 (Ans. 4). Appellants on the other hand contend that "nothing in Bluestein would disclose or suggest to a person of ordinary skill in the art a computer implemented method for <u>preparing a binding-ready biological sample</u> (ferritin) for a binding assay (immunoassay). The Bluestein reference only describes an automated method for the immunoassay" (App. Br. 5). We agree with Appellants.

Bluestein discloses a method for providing improved heterogeneous fluorescence assays using a kit with prepared samples (e.g., ferritin-containing solutions) and utilizing a SCREEN MACHINE system (FF 1-4). The Examiner suggests that Bluestein in column 8 discloses preparing an experiment design for generating a binding-ready biological sample. However, we find no such teachings in Bluestein. Instead, the cited sections of Bluestein appear to focus mainly on maintaining assay precision and accuracy instead of preparing binding-ready biological samples to be used in the assays. While we agree that Bluestein discloses biological samples (e.g., ferritin-containing solutions) to be used in an assay, the Examiner has not shown, and we do not readily find, where Bluestein discloses preparing an experiment design for generating such samples. As such, we can only rule on the basis of the evidence that is provided in support of the rejection, and we find it deficient. The allocation of burdens requires that the USPTO

Appeal 2008-3527 Application 10/734,063

produce the factual basis for its rejection of an application under 35 U.S.C. §§ 102 and 103. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (citing *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967)). The one who bears the initial burden of presenting a prima facie case of unpatentability is the Examiner. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Again, we find that the factual basis that the Examiner is relying on in Bluestein (and Lucas) deficient to show the above-noted features.

Therefore, we find that the Appellants have established that the Examiner erred in his findings. Therefore, we reverse the rejection of claim 14-22.

VI. CONCLUSIONS

We conclude that Appellants have shown that the Examiner erred in rejecting claims 14-22.

VII. DECISION

In view of the foregoing discussion, we reverse the Examiner's rejection of claims 14-22.

REVERSED

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